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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/814,689

03/31/2004

Anthony D. Cristillo

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05/30/2007

REED SMITH, LLP

ATTN: PATENT RECORDS DEPARTMENT

599 LEXINGTON AVENUE, 29TH FLOOR

NEW YORK, NY 10022-7650

EXAMINER

HUMPHREY, LOUISE WANG ZHIYING

ART UNIT

PAPER NUMBER

1648

MAIL DATE

DELIVERY MODE

05/30/2007

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/814,689

Applicant(s)

CRISTILLO ET AL.

Examiner

Louise Humphrey, Ph.D.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 09 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 13-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 25-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

This Office Action is in response to the amendment filed 09 March 2007. New claims 25-28 have been added. Claims 1-28 are pending. Claims 13-24 are withdrawn. Claims 1-12 and 25-28 are under final rejection.

#### ***Claim Rejections - 35 USC § 112 – New Matter Rejection***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 2 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. This is a NEW MATTER rejection.

The new limitations “wherein the viral protein is not a protein of the Rous sarcoma virus”, “PPX<sub>1</sub>Y” and “YX<sub>2</sub>X<sub>3</sub>L” as recited in claims 1 and 2 are not supported by the original disclosure or claims as filed.

The specification as filed does not provide sufficient written description of the above-mentioned “limitations”. The specification does not provide sufficient support for the viral budding mediating motifs PPX<sub>1</sub>Y and YX<sub>2</sub>X<sub>3</sub>L. The specification only discloses PTAP (SEQ ID NO:1), PPXY (SEQ ID NO:2), and YXXL (SEQ ID NO:3) (see paragraph 65-67); the instant claims now recite PPX<sub>1</sub>Y and YX<sub>2</sub>X<sub>3</sub>L, which were not disclosed in

the specification. Therefore, the claims represent a departure from the specification and claims as originally filed. Applicant's reliance on generic disclosure (the budding mediating motif of a viral protein) and the limited species disclosed in Table 1 do not provide sufficient direction and guidance to the features currently claimed (PPX<sub>1</sub>Y and YX<sub>2</sub>X<sub>3</sub>L). It is noted that a generic or a sub-generic disclosure cannot support a species unless the species is specifically described. It cannot be said that a subgenus is necessarily described by a genus encompassing it and a species upon which it reads. See *In re Smith* 173 USPQ 679 683 (CCPA 1972) and MPEP §2163.05.

Furthermore, the recitation of "wherein the viral protein is not a protein of the Rous sarcoma virus" is a negative limitation that is not supported by the original disclosure. Applicants are advised that adding the express exclusion of certain elements implies the permissible inclusion of all other elements not so expressly excluded. This clearly illustrates that such negative limitation does, in fact, introduce new concepts. Any negative limitation or exclusionary proviso must have basis in the original disclosure. See *Ex parte Grasselli*, 231 USPQ 393 (Bd. App.1983), *aff'd mem.*, 738 F.2d 453 (Fed. Cir. 1984). In the instant case, the specification explicitly includes Rous sarcoma virus protein in Table 1.

Such limitations recited in the present claims, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. §112. Applicant is required to cancel the new matter in the response to this Office Action. Alternatively, applicant is invited to provide sufficient written support for the "limitations" indicated above. See MPEP §714.02, 2163.05-06

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 1-5, 13-15, 17, and 18 under 35 U.S.C. §102(b) as being anticipated by Xiang *et al.* (1996) is **withdrawn** in response to Applicants' amendment adding the new matter limitation "wherein the viral protein is not a protein of the Rous sarcoma virus" in claim 1, which necessitates the following new rejections:

Claims 1-7, 9-12, 26, and 27 are rejected under 35 U.S.C. §102(b) as being anticipated by González *et al.* (1996).

The instant claims are drawn to a DNA molecule comprising a nucleic acid comprising a deletion mutation of the budding mediating motif of a SIV viral protein encoded by the nucleic acid and is associated with the virus budding process.

González *et al.* teach a plasmid comprising SIV nucleic acid comprising a deletion mutation in *gag* gene at the C-terminus, where the PTAP motif is located, according to Figure 1. The deletion mutant nucleic acid is introduced into a vector also comprising SIV PR gene, which encodes for the SIV protease. See page 6385, left column and Figure 1. Thus, the instant invention is anticipated by González *et al.*

Claims 1-6, 10-12, 27, and 28 are rejected under 35 U.S.C. §102(b) as being anticipated by Yuan *et al.* (1996).

The instant claims are drawn to a DNA molecule comprising a nucleic acid comprising a deletion mutation of the budding mediating motif of a Moloney murine leukemia virus (MMLV) viral protein encoded by the nucleic acid and is associated with the virus budding process, wherein the budding mediating motif consists of PPPY.

Yuan *et al.* teach several plasmids carrying a deletion that removes 5 amino acids, DPPPY, from MMLV Gag p12 protein, or a deletion of the entire p12 region. See page 7251, left column, Plasmids and mutants, Figure 1. Thus, the instant invention is anticipated by Yuan *et al.*

Claims 1-6, 10-12, 25 and 27 are rejected under 35 U.S.C. §102(b) as being anticipated by Wilk *et al.* (2001).

The instant claims are drawn to a DNA molecule comprising a nucleic acid comprising a deletion mutation of the budding mediating motif of a HIV viral protein encoded by the nucleic acid and is associated with the virus budding process.

Wilk *et al.* teach DNA constructs comprising genes encoding for HIV-1 Gag and a deletion of the p6 protein. The DNA constructs are cloned into baculovirus vectors. See page 761, Figure 1. The HIV-1 Gag p6 protein comprises the PTAP motif, according to paragraph [0065] in the specification. Thus, the instant invention is anticipated by Wilk *et al.*

Claims 1-12, 25 and 27 are rejected under 35 U.S.C. §102(b) as being anticipated by Royer *et al.* (1997).

The instant claims are drawn to a DNA molecule comprising a nucleic acid encoding for a HIV viral protein comprising a deletion mutation at the budding mediating motif and encoding for one or more additional viral protein.

Royer *et al.* teach a DNA construct comprising deletion of HIV-1 Gag p6, the region containing the budding mediating motif, PTAP (SEQ ID NO:1). Ach7fs encodes for p6-deleted HIV-1 Gag and HIV-1 Pol, which contains reverse transcriptase (RT) and integrase (IN). The construct is in the pGmAc115T intermediate vector. See page 133, Figure 2. Thus, the instant invention is anticipated by Royer *et al.*

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The rejection of claims 8 and 9 under 35 U.S.C. §103(a) as being obvious over Huang *et al.* (1995 in IDS) in view of Xiang *et al.* (1996) is **withdrawn** in response to Applicants' amendment adding the new matter limitation "wherein the viral protein is not a protein of the Rous sarcoma virus" in claim 1.

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### ***Conclusion***

Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

### ***Correspondence***

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise Humphrey, Ph.D. whose telephone number is 571-272-5543. The examiner can normally be reached on Mon-Fri, 9:30 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campbell, can be reached at 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Jeffrey Parkin, Ph.D.  
Primary Examiner  
23 May 2007



Louise Humphrey, Ph.D.  
Assistant Examiner